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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,553	07/06/2006	Jac-Kwan Hwang	20020-05USA	4188

7590 05/24/2010  
JHK Law  
P.O BOX 1078  
La Canada, CA 91012-1078

EXAMINER
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RAO, SAVITHA M

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,553	<b>Applicant(s)</b> HWANG ET AL.	
	<b>Examiner</b> SAVITHA RAO	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 4-5 are pending. Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 02/19/2010 are acknowledged. Claims 4-5 are amended and are under consideration in the instant office action.

Applicants' arguments, filed 02/19/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Rule 37 CFR 1.132 Declaration***

Applicant's submission of declarations under 37 CFR 1.132 filed 02/19/2010 is acknowledged. The declarations are persuasive to overcome the second 103 (a) rejection of claims 4-5, as being unpatentable over Dorman et al. ( Journal of Applied Microbiology, 2000, 88, 308-316), as evidenced by Woo et al. (Phytochemistry, Volume 26, issue 5, 1987 pages 1542-1543, Abstract only), which is hereby withdrawn in the instant action.

***Claim Rejections - 35 USC § 103***

***New Grounds of Rejection***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Claims 4- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neiss (EP 0297733, referenced in the IDS dated 07/06/2006), in view of Deac et al. (abstract only, Iqiena (1970), volume 19 (3), pages 167-73), as evidenced by Gibson (Journal of Antimicrobial chemotherapy, 1980, pages 538-570)**

Neiss teaches pharmaceutical compositions comprising catecholic butane for the treatment of acne (abstract). Neiss additionally teaches that the compounds according to his invention are useful in the treatment of diseases and disorders of the skin, such as acne and psoriasis, and in the healing of skin wounds and breaks in the skin. The compounds also have antibacterial uses (page 2, lines 7-9 and page 4, lines 20-22). Neiss teaches compositions for topical application comprising catecholic butanes of the formula:



wherein  $R_1$  and  $R_2$  are independently H, lower alkyl, lower acyl, or alkylene;  
 $R_3$ ,  $R_4$ ,  $R_5$ ,  $R_6$ ,  $R_{10}$ ,  $R_{11}$ ,  $R_{12}$ , and  $R_{13}$  are independently H or lower alkyl;  
 $R_7$ ,  $R_8$  and  $R_9$  are independently H, hydroxy, lower alkoxy, lower acyloxy, or any two adjacent groups together may be alkylene dioxy.

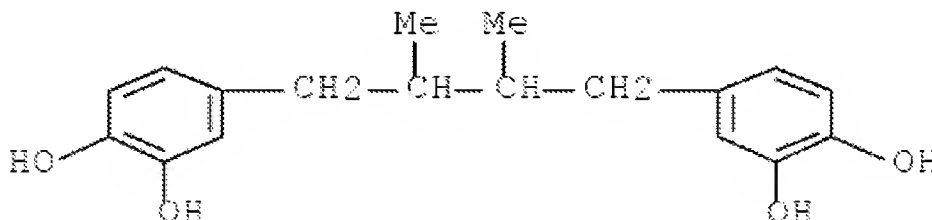
A catecholic butane of formula (II) above, where in  $R_1$ ,  $R_3$  and  $R_4$  are  $\text{CH}_3$ ,  $R_2$ ,  $R_5$ ,  $R_6$ ,  $R_9$ ,  $R_{10}$ ,  $R_{11}$ ,  $R_{12}$  and  $R_{13}$  are all hydrogen and  $R_7$  and  $R_8$  together form a alkylene (methylene) dioxy group, is a diastereoisomer of the instantly claimed macelignan (*erythro* {(4-hydroxy,-3-methoxyphenyl)-4-(3,4, methlenedioxyphenyl)-2,3-dimethyl butane}). Neiss teaches the compounds of formula (II) include compounds as a

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single optical isomer or a racemic mixture of such isomers or distereoisomers (page 5, lines 14-15). As such, Neiss provides an ordinarily skilled artisan motivation to use catecholic butanes, including {(4-hydroxy,-3-methoxyphenyl)-4-(3, 4, methlenedioxyphenyl)-2, 3-dimethyl butane}} and its diastereoisomer, which is the instantly claimed macelignan.

Neiss dose not teach specific inhibition of acne causing bacteria such *propionibacterium acnes*, *staphylococcus epidermis* and *staphylococcus aureus* as instantly claimed.

However, Deac et al. teaches nordihydroguaiaretic acid (structure shown below) to have a bactericidal effect on *Staphylococcus aureus in vitro*



The compound taught by Deac et al., nordihydroguaiaretic acid, is the preferred compound which has utility in the method of treatment of acne, taught by Neiss et al., where in the catecholic butane encompassed by the of formula (II) of Neiss shown above has in R<sub>1</sub>, R<sub>2</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub>, R<sub>8</sub>, R<sub>9</sub>, R<sub>10</sub>, R<sub>11</sub>, R<sub>12</sub> and R<sub>13</sub> are R<sub>3</sub> and R<sub>4</sub> are CH<sub>3</sub>. It is noted that the closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See, e.g., *Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (and

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cases cited therein). *Cf. Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552. As such, Macelignan and its diastereoisomer disclosed as a subgenus of the compounds which also encompasses the compound taught by Deac et al. would also be expected to have antibacterial activity against *S. aureus* similar to the compound taught by Deac et al.

Further, it is well known in the art that acne is caused by bacteria such as *propionibacterium acnes*, *staphylococcus epidermis* and *staphylococcus aureus*, as evidenced by Gibson (page 2, left column, 1<sup>st</sup> paragraph). Neiss teaches treatment of acne with compounds structurally similar to the instantly claimed compounds and, as such inhibition of the growth of these bacteria in acne lesions is a functional limitation of the compounds taught by Neiss. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). It is also noted that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such, the instantly claimed mechanistic functions of the compounds to inhibit acne-causing bacteria would be

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present in the identical compounds taught by Neiss and would therefore elicit these effects whenever it is administered for the treatment of acne.

In view of the foregoing references, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a method of treating acne comprising administering to a subject the instantly claimed macelignan. Neiss provides explicit teachings that a compound which is a structural isomer of the instantly claimed macelignan is useful in the treatment of acne, as an antibacterial, and suggests a diastereoisomer of the compounds of his teachings would also have the same utility. Deac et al. teaches nordihydroguaiaretic acid, which is also encompassed by the genus of compounds taught by Neiss, has antibacterial activity against *S. Aureus*. An ordinarily skilled artisan would therefore be motivated to utilize macelignan for treatment of acne which is characterized by the activity of the bacteria *propionibacterium acnes* and those of staphylococcus species. As such, an ordinarily skilled artisan would have a reasonable expectation of success that macelignan would provide a treatment option for acne.

### **Conclusion**

Claims 4-5 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/  
Examiner, Art Unit 1614

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614  
May 22, 2010